



UNITED STATES DEPARTMENT OF COMMERCE
Patent and Trademark Office
ASSISTANT SECRETARY AND COMMISSIONER
OF PATENTS AND TRADEMARKS
Washington, D.C. 20231

AUG - 3 1999

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Margaret Brumm
Eli Lilly and Company
Patent Division/MMB
Lilly Corporate Center
Indianapolis, IN 46285

Re: Patent Term Extension
Application for
U.S. Patent No. 4,808,614

Dear Ms. Brumm:

A certificate under 35 U.S.C. § 156 is enclosed extending the term of U.S. Patent No. 4,808,614 for a period of 1,537 days. While a courtesy copy of this letter is being forwarded to the Food and Drug Administration (FDA), you should directly correspond with the FDA regarding any required changes to the patent expiration dates set forth in the Patent and Exclusivity Data Appendix of the Orange Book (Approved Drug Products with Therapeutic Equivalence Evaluations) or in the Patent Information set forth in the Green Book (FDA Approved Animal Drug Products).

Telephone inquiries regarding this communication should be directed to the undersigned at (703)306-3159.

Karin Tyson
Legal Advisor
Special Program Law Office
Office of the Deputy Assistant Commissioner
for Patent Policy and Projects

cc: David T. Read
Acting Director Regulatory Policy Staff, CDER
Food and Drug Administration
1451 Rockville Pike, HFD-7
Rockville, MD 20852

Re: GEMZAR® (gemcitabine)
FDA Docket No. 96E-0314

UNITED STATES PATENT AND TRADEMARK OFFICE

CERTIFICATE EXTENDING PATENT TERM
UNDER 35 U.S.C. § 156

PATENT NO. : 4,808,614
ISSUED : February 28, 1989
INVENTOR(S) : Larry W. Hertel
PATENT OWNER : Eli Lilly and Company
PRODUCT : GEMZAR® (gimcitabine)

This is to certify that there has been presented to the

COMMISSIONER OF PATENTS AND TRADEMARKS

an application under 35 U.S.C. § 156 for an extension of the patent term. Since it appears that the requirements of the law have been met, this certificate extends the term of the patent for the period of

1,537 days

from February 28, 2006, the original expiration date of the patent, subject to the provisions of 35 U.S.C. § 41(b), with all rights pertaining thereto as provided by 35 U.S.C. § 156(b).



I have caused the seal of the Patent and Trademark Office to be affixed this 27th day of July 1999.

A handwritten signature in cursive script, reading "Q. Todd Dickinson", is written over a horizontal line.

Q. Todd Dickinson
Acting Assistant Secretary of Commerce and
Acting Commissioner of Patents and
Trademarks